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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/631,981
Filing Date: July 31, 2003
Appellant(s): MARTINEZ, GEORGE

Charles E. Fredericks
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/04/09 appealing from the Office action mailed 03/10/09.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0169473	SEPETKA	11-2002
7,066,904	ROSENTHAL	06-2006

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka (US 2002/0169473) in view of Rosenthal (US 7,006,904) further in view of Kopecek (WO 98/01421).

Sepetka discloses a vaso-occlusive device implant, comprising: an elongate, flexible, filamentous inner element (352); a non-metallic intermediate element coaxially surrounding the inner element and in intimate contact therewith substantially along the length of the inner member (Para [0164] where the intermediate element is drug coating); and an outer element coaxially surrounding the intermediate element and in intimate contact therewith (354), the outer element defining a gap or opening through which the intermediate element is exposed and through which the intermediate element is capable of swelling (see for example Figs 62-64, 67, 68). The inner element comprises a microcoil (in the sense that micro is extremely small and therefore the limitation is not being given patentable weight). The outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed. The proximal and distal end sections of the outer element are respectively attached to the distal and proximal ends of the inner element (although not necessarily fixedly attached, the coils are attached in the sense that are joined together as one element). Each of the proximal and distal end sections of the outer element includes a close- wound helical coil section (for example Fig. 67, 68).

Sepetka does not disclose the intermediate element being an expansile polymeric material that is a hydrogel. Sepetka does disclose that an intermediate element that is for providing drug delivery. However, Rosenthal teaches an expansile polymeric material element that is for providing drug delivery and consists essentially of hydrogel (C3:L37-39; C4:L6, 11). The hydrogel expands in response to change in temperature or pH (C 3: L33-41; C4:L10-14). All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention, namely a way of delivering a drug in a controlled manner via the use of hydrogel and a triggering mechanism. The use of hydrogel and a triggering mechanism allows the user to have full control over timing of the drug delivery thus preventing the drug from being released prematurely. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

The modified device would meet the limitation that the intermediate element, when expanded, extends though the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments. Sepetka discloses the use of one coil as the outer element (Para [0164] *one or more secondary coils*) It is well known in the art that hydrogels can expand up to 600 times their original size. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01).

Sepetka modified by Rosenthal does not disclose explicitly that the hydrogel is *capable of* expanding at a controlled rate but does disclose that it is expanded by a change in temperature or pH. Kopecek also teaches the use of hydrogel to deliver drugs to the body. Kopecek further teaches that it is known in the art for hydrogels to swell at a chemically controlled rate when there is a change in pH. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the feature of controlled expansion of the hydrogel to further control the delivery of the drug to the vessel and prevent trauma to the vessel that may be encountered from the hydrogel expanding too quickly or forcefully. Kopecek teaches that the feature is known in the art and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

Sepetka in view of Rosenthal and Kopecek does not disclose a coupling element attached to the proximal end of the inner element and to the proximal end of the outer element. It would have been well within the skill of the ordinary artisan to incorporate a coupling element at the proximal ends of the coils since it is old and well known to use coupling elements (i.e. welds, radiopaque markers, sutures) in medical implants having coaxially surrounding elements (i.e. embolic coils, stent-grafts, embolic filters). The common knowledge or well-known in the art statement is taken to be admitted prior art because applicant has failed to traverse the examiner's assertion of official notice

(10) Response to Argument

Applicant's representative first presents that the claim recites an expansile element capable of expanding to fill an aneurysm and argues that the device shown in the Sepetka publication cannot be positioned within an aneurysm because of its size, shape and flexibility. The claimed recitation does not require that the device be positioned within the aneurysm, but rather requires that the expansile element be *capable* of expanding to fill the aneurysm, which examiner asserts it is met by the combination of Sepetka in view of Rosenthal. The configuration shown for example in Fig. 69 further supports that the device in Sepetka can be positioned within an aneurysm and thus the hydrogel on the coils would be capable of filling the aneurysm when it expands. Note that there is no requirement on how much hydrogel must enter the aneurysm in order to fill it. Thus any expansion of the hydrogel will fill the aneurysm at least partially thereby meeting the claimed limitation. It is further noted that aneurysms exist in all different shapes and sizes in many differently sized animals and so the limitation "capable of filling an aneurysm" is relative to the particular aneurysm.

Applicant's representative presents that none of the references teach that hydrogel expands at a controlled rate, particularly Kopecek which examiner is relying on as a teaching reference. The argument is that Kopecek swells at a controlled rate to time its release at a specific point in the intestinal track and preventing expansion as it travels through the more acidic stomach and thus the Kopecek hydrogel is narrowly tailored for specific series of environmental changes that occur within the intestinal tract. Applicant's representative concludes that since the blood in the aneurysm has a

different pH and different enzymes, the hydrogel of Kopecek would be not triggered to expand in a controlled manner in the blood of an aneurysm. The rejection does not rely on the specific hydrogel and the specific parameters of the swelling taught by Kopecek in order to meet the limitations of the claims. Note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Kopecek is used to provide evidence that it is known in the art that the rate of expansion can be controlled by the change in pH. Rosenthal clearly teaches that the expansion of the hydrogel reacts to a change in pH. It would be well within the skill of the ordinary artisan to use the teaching of Kopecek, i.e. a change in pH and enzymatic activity, in order to control the rate of expansion of the hydrogel in Rosenthal to better control the release of drugs over a period of time. Further, examiner asserts that the limitation "at a controlled rate" is not as limiting as applicant's representative sets forth. Even without the evidence of Kopecek that it is known to control the rate of expansion, the combination of Sepetka and Rosenthal alone inherently meets the limitation. A hydrogel necessarily expands at some rate of expansion. The issue that the rate of expansion is not controlled by an outside element is irrelevant. Any rate of expansion is considered a controlled rate of expansion since there are no structural limitations in the claims directed toward what element is controlling the rate. Further the rate of

expansion, whatever it may be, is controlled by the trigger mechanism that initiates the expansion. Kopecek merely provides further evidence that the rate can be controlled by the change in pH and enzymes.

Applicant's representative argues that Rosenthal's hydrogel would be insufficient to fill the aneurysm. As stated above, there is no limitation on how much hydrogel must enter the aneurysm to fill it. Thus any hydrogel that enters the aneurysm and at least partially fills it meets the limitations of the claim.

Applicant's representative states that the examiner's prima facie case of obviousness is flawed since the rejection relies on drug delivery which is not mentioned in the claims. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Finally, applicant's representative sets forth that examiner has failed to address the contents of many of the dependent claims. Examiner asserts that all the claims have been addressed in the Final Action of March 10, 2009 as well as in all previous actions and points out that applicant's representative made no mention of missing elements in any previous communication. Regarding the footnote on page 11 of the Brief, the examiner is not required to present every dependent claim individually word for word as long as all the limitations of the claim are addressed. For example, regarding claim 2, the microcoil is clearly addressed in lines 9 and 10 of the first paragraph of the rejection (Para 5 of the action dated 03/10/99). Regarding claims 9, 24, 48 and 62, the undulating

configuration is addressed in line 3 of the fourth paragraph of the rejection (Para 8 of the action dated 03/10/99). Regarding claims 4, 19, 25, 31, 36, 43 and 57, the gaps defined by the open-wound coil are addressed in lines 6-7 of the first paragraph (Para 5 of the action dated 03/10/99).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Elizabeth Houston/
Examiner, Art Unit 3731

Conferees:

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

Michael Milano
/Michael J Milano/
Primary Examiner